IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

BIOVAIL CORPORATION
7150 Mississauga Road
Mississauga, Ontario
Canada L5N 8M5

and

BIOVAIL LABORATORIES INTERNATIONAL SRL,
Chelston Park, Building 2, Ground Floor
Collymore Rock, St. Michael
Barbados, West Indies

Plaintiffs,

v.

U.S. FOOD AND DRUG ADMINISTRATION
5600 Fishers Lane
Rockville, Montgomery County, MD 20857

and

ANDREW C. VON ESCHENBACH, M.D.,
In His Official Capacity as
Commissioner of Food and Drugs,
U.S. Food and Drug Administration
5600 Fishers Lane
Rockville, Montgomery County, MD 20857

Defendants.

COMPLAINT FOR INJUNCTIVE AND DECLARATORY RELIEF

INTRODUCTION

1. Plaintiffs Biovail Corporation and Biovail Laboratories International SRL (collectively, "Biovail") bring this action for injunctive and declaratory relief against the U.S. Food and Drug Administration ("FDA") and its Commissioner of Food and Drugs. This action seeks a declaration that the FDA's approval of the commercial manufacture, use or sale of 300mg Bupropion XL shall not be effective until the expiration of a thirty-month period beginning from the filing of Abbreviated New Drug Application 77-415 ("ANDA 77-415"), as provided in 21 U.S.C. § 355(j)(5)(B)(iii). Plaintiffs further seek temporary and preliminary injunctive relief enjoining the FDA from taking any action to effect its putative approval pending the resolution of this matter.

2. Upon receiving notice of the filing of ANDA 77-415 for approval, Biovail made a good faith determination that the ANDA infringed Biovail's patent rights and timely filed an infringement suit. By statute, Biovail's filing of suit required the FDA to stay any final approval of ANDA 77-415 for 30 months. Nonetheless, and in violation of the plain language of that statute, the FDA has purported to issue a final and effective approval of the 300mg dosage of that ANDA.

JURISDICTION AND VENUE

3. This Court has jurisdiction over this action pursuant to the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 555, 702 and 706; and 28 U.S.C. § 1331 (federal question).

4. The relief requested is authorized pursuant to 28 U.S.C. § 2201 (declaratory relief); and 28 U.S.C. § 2202 (further relief). Plaintiffs have a right to bring this action pursuant to the APA, 5 U.S.C. §§ 701-706.

5. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e).

PARTIES

6. Plaintiff Biovail Corporation is a corporation with its head office at 7150 Mississauga Road, Mississauga, Ontario, Canada, L5N 8M5. Biovail, together with its subsidiaries, is a fully integrated pharmaceutical company that, among other things, tests, develops, manufactures, and sells prescription drugs, either directly or to other pharmaceutical companies for marketing and distribution primarily in the U.S. and Canadian markets. The company is listed and publicly traded on the New York and Toronto Stock Exchanges.

7. Plaintiff Biovail Laboratories International SRL is a wholly owned subsidiary of Biovail Corporation, with its offices located at Chelston Park, Building 2, Collymore Rock, St. Michael, Barbados, West Indies. Biovail Laboratories International SRL is the assigned owner of the patents to WELLBUTRIN XL®.

8. Defendant U.S. Food and Drug Administration, which has its principal office at 5600 Fishers Lane, Rockville, Maryland 20857, regulates prescription drugs under authority delegated by Congress.

9. Defendant Andrew C. von Eschenbach, M.D., is sued in his official capacity as Commissioner of Food and Drugs. As Commissioner, Dr. von Eschenbach has the ultimate responsibility for the activities of FDA, including those actions complained of herein. Dr. von Eschenbach maintains an office at 5600 Fishers Lane, Rockville, Maryland 20857.

STATEMENT OF FACTS

Biovail's WELLBUTRIN XL®

10. Biovail developed and manufactures WELLBUTRIN XL®. WELLBUTRIN XL® is an FDA-approved "innovator" prescription drug (sometimes referred to as a "pioneer," "brand-name" or

"branded" drug) used to treat Major Depressive Disorder ("MDD"), a common and severe psychiatric disorder.

11. WELLBUTRIN XL® was approved for manufacture, market and sale by the FDA on August 28, 2003, under New Drug Application 021515. The owner of the rights under that New Drug Application is SmithKline Beecham Corp. ("SmithKline"), which has an exclusive license under U.S. Patent No. 6,096,341 (the "'341 patent"), which covers WELLBUTRIN XL®.

12. Biovail manufactures and supplies WELLBUTRIN XL® for the U.S. market exclusively to GlaxoSmithKline, Inc., one of the largest pharmaceutical companies in the world. Biovail is the owner by assignment of the '341 patent, has the right to sue for patent infringement and to recover any damages associated with the infringement.

13. WELLBUTRIN XL® represents a substantial asset and cash flow stream for Biovail, generating hundreds of millions of dollars a year in revenue.

14. Chemically, WELLBUTRIN XL® is bupropion hydrochloride in extended-release tablets for once-a-day-administration.

15. Under relevant provisions of the Federal Food, Drug, and Cosmetic Act, as amended, 21 U.S.C. § 321, *et seq.* ("FDCA"), parties are permitted to file Abbreviated New Drug Applications ("ANDAs") for generic forms of FDA-approved innovator drugs such as WELLBUTRIN XL®. A generic version of an innovator drug may be approved under an ANDA that relies upon the findings of safety and effectiveness for the innovator drug.

16. However, because a generic is marketed as a substitute for an innovator drug, FDA may not approve an ANDA unless the applicant proves that its generic version is "bioequivalent" to the innovator drug.

17. Further, in order to protect the patent rights of the owner and manufacturer of the pioneer drug, any applicant filing an ANDA is required to provide notice of the ANDA filing to the entities with patent rights and to set forth the bases of the applicant's opinion that those patent rights are invalid or not infringed by the ANDA. This notice is known as a "Paragraph IV Certification Notice."

18. Receipt of the Paragraph IV certification permits the patent holder to initiate an immediate patent infringement suit.

19. If the patent holder files a patent infringement suit within 45 days from the receipt of Paragraph IV Certification Notice, the ANDA may not be approved by the FDA until the expiration of 30 months from the date the Paragraph IV Certification Notice was received or the resolution of the infringement suit, whichever is shorter.

The Infringement Suit Against ANDA 77-415

20. On or about January 20, 2005, Impax Laboratories, Inc. ("Impax") sent a Paragraph IV Certification Notice to Biovail noticing its submission to the FDA of ANDA 77-415 for Impax's bupropion hydrochloride 150mg extended release tablets. Biovail received the Notice on or about January 24, 2005.

21. On or about January 24, 2005, Impax provided a Paragraph IV Certification Notice of an amendment to its ANDA 77-415, providing for the addition of a 300mg tablet.

22. Biovail reviewed ANDA 77-415, and made a good faith determination that it infringes on the '341 patent. Accordingly, on March 7, 2005, Biovail filed an action for patent infringement in the United States District Court for the Eastern District of Pennsylvania, *Biovail Laboratories, Inc. v. Impax Laboratories, Inc.*, No. 05-cv-1085 (the "Patent Infringement Action").

23. The Patent Infringement Action sought, *inter alia*, a judgment that ANDA 77-415 infringed the '341 patent; an order that ANDA 77-415 not be effectively approved until the expiration of the '341 patent; and an injunction prohibiting the commercial manufacture, use or sale of any product made pursuant to ANDA 77-415.

24. The Patent Infringement Action was timely filed pursuant to the 45-day provisions, and is currently pending. Thus, the mandatory 30-month stay period was triggered, and no approval of ANDA 77-415 could become effective until the expiration of 30 months or the resolution of the Patent Infringement Suit, whichever comes first.

FDA's Unlawful Approval of the ANDA

25. On December 15, 2006, the FDA advised Biovail that it intended to issue an immediately effective approval for the amendment to the ANDA 77-415. This approval would permit Impax to immediately manufacture and sell 300mg tablets made pursuant to the specifications of ANDA 77-415.

26. The FDA's approval violates the mandatory, statutory 30-month stay to which Biovail is entitled.

27. As a result of the FDA's unlawful approval of the amendment to ANDA 77-415, Impax will be able to manufacture and sell products made pursuant to the specification of ANDA 77-415 while the Patent Infringement Suit is pending.

28. This Complaint asks that the Court exercise its constitutional and statutory prerogative to conduct a judicial review of this erroneous and unlawful FDA approval.

CLAIM

29. Biovail incorporates by reference all allegations contained in paragraphs 1 through 28 of this Complaint.

30. The FDA approval of the 300mg amendment to ANDA 77-415, notwithstanding the Patent Infringement Action, was arbitrary, capricious, an abuse of agency discretion, and contrary to the FDCA and the APA.

31. Biovail is in imminent danger of losing its statutory rights to exclusivity and to have the patent issues raised by its Patent Infringement Suit resolved before a potentially infringing drug is permitted to market, as a direct result of the FDA's improper approval of the ANDA amendment.

32. Biovail is also in imminent danger of losing sales to Impax as a direct result of FDA's improper approval of the ANDA amendment.

33. As a result of FDA's actions, Biovail has suffered and will continue to suffer, absent injunctive relief, irreparable harm for which there is no adequate remedy at law.

RELIEF REQUESTED

WHEREFORE, plaintiffs respectfully request that this Court enter an order:

A. Declaring that FDA's approval of the Impax ANDA amendment was arbitrary, capricious, an abuse of agency discretion, and contrary to the FDCA and the APA;

B. Directing the FDA to withdraw or suspend the approval of the Impax ANDA amendment until the expiration of 30 months or the resolution of the Patent Infringement Suit, whichever is earlier;

C. Temporarily, preliminary and permanently enjoining FDA from making effective the approval of ANDA 77-415 or any amendments thereto until the expiration of 30 months or the resolution of the Patent Infringement Suit, whichever is earlier;

D. Awarding plaintiffs' attorneys' fees and reasonable expenses incurred in connection with this action; and

E. Such other relief as the Court deems just and proper.

Dated: December 18, 2006

Respectfully submitted,

By: _____

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